

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Michael A. Zeligs	Confirmation No.:	
Serial No.:	To be assigned	Art Unit:	1615
Filed:	On even date herewith	Examiner:	To be assigned
For:	Phytochemical for the Treatment of Mastalgia, Endometriosis and HPV-related Conditions Including Cervical Dysplasia	Attorney Docket No.:	9439-015

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
  - 1b. A legible copy of :
    - ☒ Each U.S. patent application publication and U.S. and foreign patent;
    - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
    - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
    - ☐ all other information or portion which caused it to be listed on the PTO-1449.
  - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - ☒ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☐ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.
- (Check either Item 3a or 3b)*
- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.
- The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:
- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

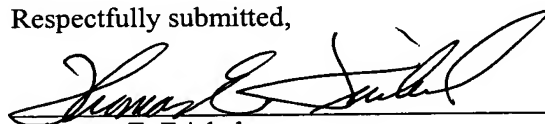
- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: July 9, 2003



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**LIST OF REFERENCES CITED BY REQUESTOR**

(Use several sheets if necessary)

ATTY DOCKET NO.

9439-015-999

APPLICATION NO: To be assigned

APPLICANT

Michael A. Zeligs

FILING DATE:

On even date herewith

GROUP

1615

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	6,086,915	07/11/2000	Zeligs			04/01/1998
	A02	5,830,887	11/3/1998	Kelly			
	A03	5,948,808	9/7/1999	Safe			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

C01	Baugh SM <i>et al.</i> , "Treatment of cervical dysplasia with indole-3-carbinol" in The Ray A. Barlow Scientific Symposium, 1998 Jan 23, Shreveport : The Center for Excellence in Cancer Research, Treatment and Education, Louisiana State University Medical Center, Shreveport (LA), pg. 3. *
C02	Bell, MC <i>et al.</i> , "Placebo-controlled Trial of Indole-3-Carbinol in the Treatment of Cervical Dysplasia", 1999 March, Gynecol. Oncol. 72:446
C03	Yuan F <i>et al.</i> , "Prevention of Papillomavirus initiated cancer by the phytochemical Indole-3-Carbinol", Proceedings of the 17 <sup>th</sup> International Papillomavirus Conference, 1999 Jan 9-15, pg. 73.
C04	BioResponse-DIM Indolplex Product Information Brochure, 1998 Dec 15.
C05	December 1998 Bioresponse Letter, 1998 Dec 29.
C06	Zeligs MA, "Diet and Estrogen Status: The Cruciferous Connection", 1998, J Med Food, 1:67-82.
C07	Ponten J and Guo Z, "Precancer of the Human Cervix", 1998, Cancer Surveys 32:201-229.
C08	Cancer Medicine 3rd edition, 1993, JF Holland ed., Lea & Febiger, Malvern, PA p. 1633.
C09	Molecular Biology of the Cell 2 <sup>nd</sup> ed., 1989, Alberts, B <i>et al.</i> , Garland Publishing, Inc., New York, pp. 1193-1194, 1204-1206.
C10	Arbeit, JM <i>et al.</i> , "Chronic estrogen-induced cervical and vaginal squamous carcinogenesis in human papillomavirus type 16 transgenic mice", 1996 Apr., Proc Natl Acad Sci, USA 93:2930-2935.
C11	Bell, MC <i>et al.</i> , "Placebo-Controlled Trial of Indole-3-Carbinol in the Treatment of CIN", 2000, Gynecologic Oncology, 78:123-129.
C12	Bradfield <i>et al.</i> , "High-performance liquid chromatographic analysis of anticarcinogenic indoles in Brassica oleracea", 1987, J Agric Food Chem 35:46-49
C13	Michnovicz <i>et al.</i> , "Changes in levels of urinary estrogen metabolites after oral indole-3-carbinol treatment in humans", 1997, J Natl Cancer Inst 89:718-23
C14	Ho <i>et al.</i> , "Urinary 2/16alpha-hydroestrone ratio: correlation with serum insulin-like growth factor binding protein-3 and a potential biomarker of breast cancer risk", 1998, Ann Acad Med Singapore 27:294-9

C15	Schneider et al., "Abnormal oxidative metabolism of estradiol in women with breast cancer", 1982, Proc Natl Acad Sci USA 79:3047-52
C16	Bradlow et al., "2-hydroxyestrone: the 'good' estrogen", 1996, J Endocrin 150:S259-S265
C17	Komura et al., "Catecholestrone as a natural antioxidant", 1996, Ann NY Acad Sci 786:419-29
C18	Rosen et al., "Preliminary results of the use of indole-3-carbinol for recurrent respiratory papillomatosis", 1998, Otolaryngol Head Neck Surg 118:810-5
C19	Jin et al., "Indole-3-carbinol prevents cervical cancer in human papillomavirus type 16 (HPV16) transgenic mice", 1999, Cancer Res 59:3991-7
C20	Chen et al., "aryl hydrocarbon receptor-mediated antiestrogenic and antitumorigenic activity of diindolymethane", 1998, Carcinogenesis 19:1631-1639

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	